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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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09/972,425

10/05/2001

Kenneth C. Cundy

033053-025

5701

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08/17/2005

BUCHANAN INGERSOLL PC  
(INCLUDING BURNS, DOANE, SWECKER & MATHIS)  
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EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 08/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Supplemental  
Notice of Allowability**

Application No.

09/972,425

Examiner

Barbara P. Badio, Ph.D.

Applicant(s)

CUNDY ET AL.

Art Unit

1617

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to \_\_\_\_.
2. ☒ The allowed claim(s) is/are 1,3-6,9,10,19 and 20.
3. ☐ The drawings filed on \_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_.

Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit: 1617

Art Unit: 1617

**SUPPLEMENTAL EXAMINER'S AMENDMENT**

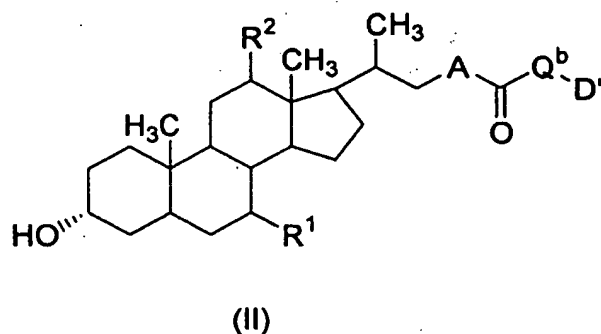
1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Melissa Hayworth on August 16, 2005.

The application has been amended as follows:

Claim 6 has been rewritten as follows: --

6. A compound of formula (II):

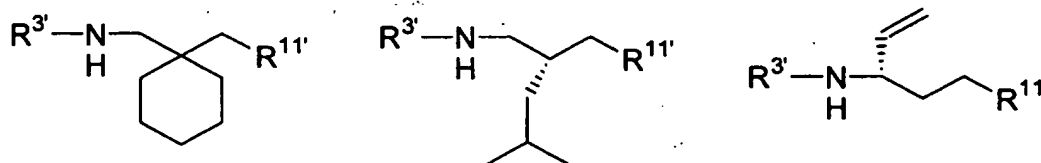


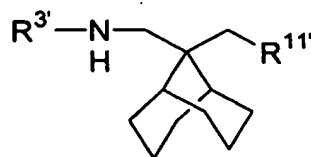
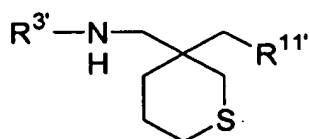
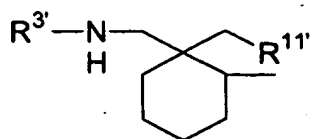
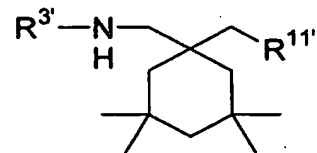
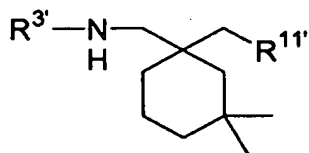
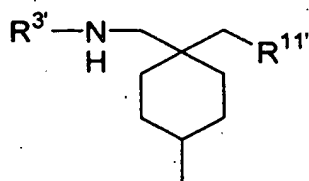
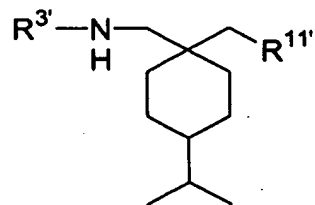
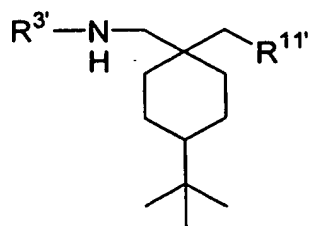
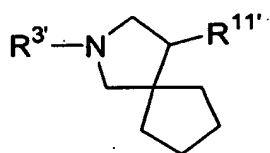
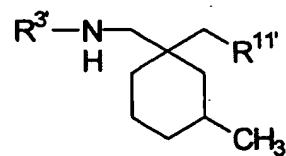
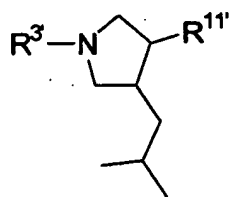
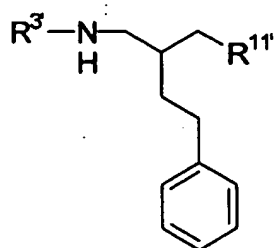
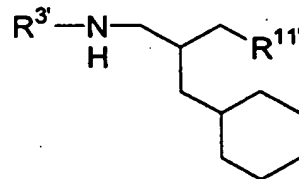
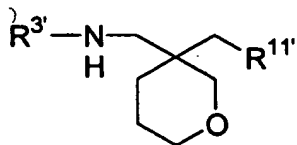
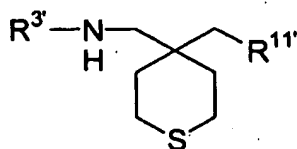
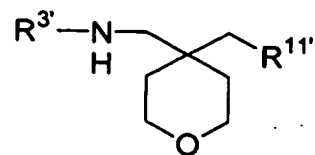
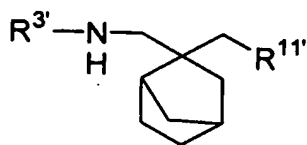
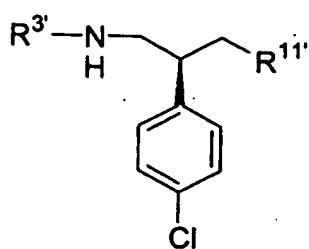
wherein:

$R^1$  and  $R^2$  are both  $\alpha$ -OH; or  $R^1$  is  $\beta$ -OH and  $R^2$  is hydrogen; or  $R^1$  is  $\alpha$ -OH and  $R^2$  is hydrogen; or  $R^1$  is hydrogen and  $R^2$  is  $\alpha$ -OH; or  $R^1$  is  $\beta$ -OH and  $R^2$  is  $\alpha$ -OH; or  $R^1$  and  $R^2$  are both hydrogen;

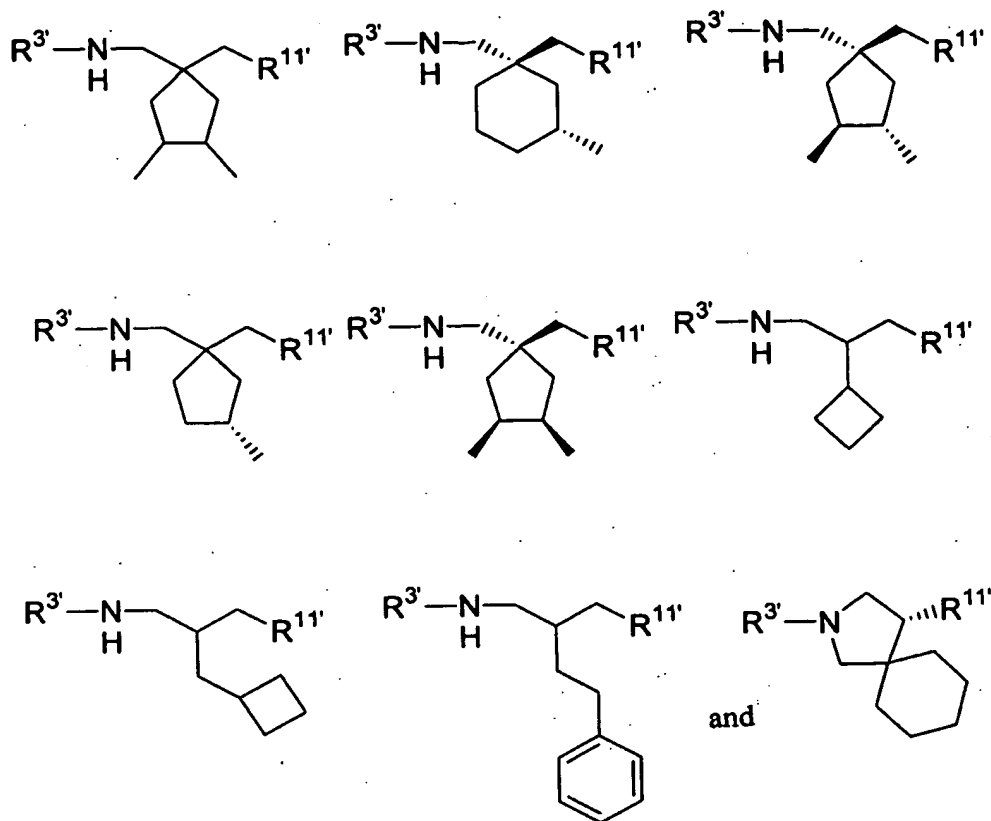
A is  $-\text{O}-$  or  $-\text{CH}_2-$ ;

$D''$  is a GABA analog moiety selected from the group consisting of:

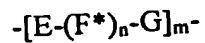




Art Unit: 1617



where

 $R^{3'}$  is a covalent bond linking  $D''$  to  $Q^b$ ; $R^{11'}$  is carboxyl acid; and $Q^b$  is a linker of the following formula:

wherein:

 $m$  is an integer of from 1 to 4; $n$  is 0 or 1; $E$  is  $-O-$ ;

F\* is selected from a group consisting of alkylene, substituted alkylene, alkenylene, substituted alkenylene, alkynylene, and substituted alkynylene; and

G is  $-C(O)-$ ;

wherein Q<sup>b</sup> is cleavable under physiological conditions provided that Q<sup>a</sup> is not a linear oligopeptide consisting of 1, 2 or 3  $\alpha$ -amino acids and/or  $\beta$ -amino acids; or a pharmaceutically acceptable salt thereof.

### ***Telephone Inquiry***


2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Art Unit: 1617

you have questions on access to the Private PAIR system, contact the Electronic  
Business Center (EBC) at 866-217-9197 (toll-free).

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1617

BB  
August 16, 2005